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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,085	01/09/2002	Patricia Lynne Conway	28053/38258	6842

7590 05/02/2006

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EXAMINER

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ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 05/02/2006

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/889,085
Filing Date: January 09, 2002
Appellant(s): CONWAY ET AL.

For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 03/03/2006 appealing from the Office action
mailed 5/31/2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings, which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is incorrect. A correct statement of the status of the claims is as follows:

This appeal involves claims 77-153.

Claims 1-19 and 42-62 are canceled by applicants.

Claims 20-40 and 63-75 are withdrawn from consideration as not directed to the elected invention(s).

Claims 41 and 76-153 are rejected in the Office action mailed 5/31/2005.

No claims are allowed.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

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The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,143,845	Masuda	9-1992
6,060,050	Brown et al.	5-2000
5,714,600	McNaught et al.	2-1998
6,221,350	Brown et al.	4-2001

Brown et al. "High amylose maize starch as a versatile prebiotic for use with probiotic bacteria" Food Australia, Vol. 50, No. 12 (December, 1998), pp. 603-610.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 41, 76, 77, 79, 81, 88, 90-105, 109-120, 124-135 and 139-150 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,143,845 (Masuda).

Claims are directed to a microbial product comprising at least one component such as “harvested” microbes that were grown/cultured on media containing resistant starch and that have improved characteristics associated with survival/recovery. Some claims are further drawn

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to incorporation of microbial products into various food, feed, pharmaceutical and bioremediation products suitable for delivery of viable microbes. Some claims are further drawn to the use of microbes including representatives of the genera *Lactobacillus*, *Bifidobacterium*, *Clostridium*, *Bacillus*, etc. in the microbial products.

US 5,143,845 discloses a microbial product that is a microbial preparation comprising symbiotic mixture of live and active bacteria (see abstract). The microbial preparations are incorporated into a pharmaceutical product comprising potato starch (col. 2, lines 45-46 or col. 3, lines 16-25) and/or into other food or feed products suitable for delivery of the live probiotic microorganisms (col. 1, line 39-40) including fluid-based products (col. 7, line 17) and/or milk derivative or milk casein containing products (col. 5, line 52). The microbes were cultured and harvested before incorporation into the products (example 2) and, thus, they are “harvested” after being cultured, activated and proliferated. The cited patent teaches that the resulting microbial preparations are capable to effectively proliferate (col. 4, lines 18), that they demonstrate satisfactory effects upon administration as related to maintenance and recovery in the digestive tract (col. 3, lines 65-68) and that they are characterized by heat stability, dry stability and drug stability (col. 2, lines 53-55). Thus, the activated microbial preparation of the cited patent are characterized by increased survival/recovery rate in a generic product and they would be substantially unaffected by stresses within the meaning of the instant claims. The microbial products of the cited patent include representatives of the genera *Lactobacillus*, *Bifidobacterium*, *Clostridium*, *Bacillus* and others (col. 2, lines 34-44) as the microbial preparations of instant claims 96-99, 111-114, 126-129, and 141-144 and, thus, the bacteria used in the cited product are capable to grown on the same substrates as the claimed bacteria. The cited patent discloses that

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various starches are used and/or suitable for growing and making microbial preparations (col. 4, lines 32-34) including potato starch, cornstarch and soluble starch. Although the cited patent is either silent or uncertain about “resistant” starches, the term “resistant” starch generally relates to digestion in mammalian intestines. The final product as claimed is not required to comprise “resistant” starch. The claimed product is one component composition.

Therefore, the cited patent US 5,143,845 discloses identical composition comprising microbial preparations comprising identical microbes that are characterized by enhanced survival, viability and recovery as required for the claimed product. Thus, the cited patent US 5,143,845 anticipates the presently claimed invention.

Claims 41 and 76-153 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,060,050 (Brown et al.) in the light of evidence by US 5,714,600 (McNaught et al.).

Claims are directed to a microbial product comprising one component such as “harvested microbes” or grown/cultured microbes that have improved characteristics associated with survival/recovery. Some claims are further drawn to incorporation of a second component such as resistant starch into the total microbial products, to the amounts of resistant starch in the total microbial products such as 0.1-90 % (w/) or about 10% (w/w). Some claims are further drawn to the use of various forms of resistant starch in the total products including resistant starches derived from maize, rice, barley, potatoes and including resistant starches having amylose content at least 70 %, 80% or 90%. Some claims are further drawn to incorporation of microbial products into various food, feed, pharmaceutical and bioremediation products suitable for delivery of viable microbes. Some claims are further drawn to the use of microbes including

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representatives of the genera *Lactobacillus*, *Bifidobacterium*, *Clostridium*, *Bacillus*, *Saccharomyces*, *Clostridium*, etc. the microbial products.

US 6,060,050 teaches a microbial preparation comprising harvested microbes with improved characteristics associated with survival/recovery in intestinal tract and it teaches incorporation of resistant starch into microbial preparations and/or into products with microbial preparations (col. 1, lines 55-65). The cited patent discloses amounts of resistant starch in the product and/or in the microbial preparations such as 2-20 % w/w (col. 2, lines 57-58) or 10% (col. 8, lines 15-25). The cited patent teaches the use of resistant starch RS1, RS2, RS3 or RS4 (col. 1, line 54) which is derived from maize, rice, barley, potatoes (col.4, lines 3-5) and to the use of maize resistant starch with amylose content of more than 50% or more than 80% (col. 3, lines 62-65). The phrase “more than” as related to the amylose content means “at least 90%” because the cited US 6,060,050 refers to the use of maize resistant starch disclosed in WO94/03049, which is equivalent to US 5,714,600, wherein the maize resistant starch having more than 80% of amylose includes amylose contents of “at least 90% “ (see US 5,714,600 col. 2, line 67). The resistant starch in the products of US 6,060,050 are also chemically or physically treated starches by chemical modification including esterification, acidification, etc. (col. 4, lines 15-21). The cited US 6,060,050 also teaches that microbes were cultured or grown on resistant starch containing media (col. 5, lines 31-36; col. 9, lines 50-55 and table 4) in order to select probiotic microorganisms that can grow on resistant starch (col. 2, lines 14-17) and to survive in the intestinal tract (col. 1, line 63-64). The microbes in the products of US 6,060,050 are characterized by a stress resistance including resistance to freezing and to freeze-drying (col. 2, line 50). The cited patent discloses to the use of various microorganisms including *Lactobacillus*,

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Bifidobacterium, Clostridium, Bacillus, Saccharomyces, Clostridium in the microbial products (col. 2, lines 20-25) and incorporation of microbial products into various food, feed, pharmaceutical and bioremediation products suitable for delivery of viable microbes (col. 4, lines 55-60).

Thus, the cited patent US 6,060,050 anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 41 and 76-153 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,143,845 (Masuda) taken with US 6,060,050 (Brown et al.), Brown et al. ("High amylase maize starch as a versalite prebiotic for use with probiotic bacteria". Food Australia 50 (12), December 1998) and US 5,714,600 (McNaught et al.).

Claims as explained above.

US 5,143,845 (Masuda) is relied upon as explained above for the disclosure of microbial product that is characterized by increased survival and recovery. The cited US 5,143,845 is silent about the use of resistant starch in the total product.

However, US 6,060,050 teaches microbial products comprising microbes and various forms of resistant starch. The cited US 6,060,050 also teaches that microbes were cultured or grown on resistant starch containing media (col. 5, lines 31-36; col. 9, lines 50-55 and table 4) in

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order to select or harvest probiotic microorganisms that grow on resistant starch (col. 2, lines 14-17) and, thus, survive in the intestinal tract and large bowel (col. 1, line 63-64).

Further, the reference by Brown et al. is relied upon for the teaching directed to beneficial properties of resistant starch and for a clear suggestion to incorporate resistant starches into microbial preparations/products for improving robustness and viability of probiotics in gastrointestinal tract and in the food products (table 2). It is also teaches that the high amylose maize resistant starch is particularly beneficial for lactic acid bacteria because it enhances bacterial survival and stress resistance (page 607, col. 1).

The cited patent US 5,714,600 is relied upon to demonstrate that physically and/or chemically modified resistant starch (col.7, lines 13-15) including maize starch having high amylose contents of at least 40-90% (col.2, lines 63-67) are available in the prior art and they have been suggested for various compositions including foods and other industrial products (col. 1, line 24).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify compositions of US 5,143,845 (Masuda) by incorporation of maize resistant starch of US 6,060,050 and/or of US 5,714,600 with a reasonable expectation of success in increasing survival and recovery of microbial preparations in various products because benefits of incorporations of resistant starch into probiotic compositions are known as adequately demonstrated by Brown et al. One of skill in the art would have been motivated to use high amylose maize resistant starch in microbial preparations/products for the expected benefits related to the improved viability and to stress

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resistance of probiotic cultures (Brown et al.). Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 41 and 76-153 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,221,350 (Brown et al.).

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both directed to microbial probiotic products comprising at least 1) probiotic microorganisms and 2) resistant starch.

Claims of US 6,221,350 appear to be narrower and they require 3 components in the product including microorganisms, resistant starch and oligosaccharide. Some of the claims of the instant application are broader and they are drawn to generic microbial products, for example: claims 41, 77, 79, 81, or 88. However, some of the claims of the instant applications are drawn to products comprising both microorganisms and resistant starch, for example: claims 78, 80, 82-87, 89, 106-108, 121-12, 136-138 and 151-153. The microorganisms in the compositions of the instant application and of the cited patent are identical, for example: see patented claims 3-6 and see instant 96-99, 111-114, 126-129 and 141-144. The resistant starch in the compositions of the instant application and of the cited patent is identical, for example: see patented claims 9-12 and instant claims 83-87. Although the claims of the instant application are not clearly directed to the use of oligosaccharides, they encompass the use of food products including confectionary, biscuits, desserts or flavored drinks that do not exclude the use of oligosaccharides or fructo-oligosaccharides and, therefore, are reasonably expected to comprises at least some amounts of oligosaccharides or fructo-oligosaccharides.

Accordingly, the claimed compositions are obvious variants. Thus, the inventions as claimed are co-extensive.

(10) Response to Argument

Applicants' main argument is directed to the idea that the claimed microbial preparation comprises those microbes that were cultured on media containing resistant starch and harvested from the media comprising resistant starch and, thus, the claimed microbes have some improved characteristics associated with survival and recovery rates (appeal brief page 5).

The presently claimed product is defined as a product-by-process. The product-by-process claims are not limited to the manipulations of the recited steps, only to the final structure of the product obtained and the patentability of a product does not depend on its method of production. MPEP 2113. In the instant claims, the final product or final microbial preparation is said to be relatively better over some generic starting microbial cells with respect to microbial survival and recovery. However, neither starting nor end products are specific microbial strains that are/would be available, reliable and characterized by some specific rates of survival and recovery. Thus, in view of a relative characterization that is defined by the structure of the instant claims, the claimed microbial product *per se* has only one final physical and/or measurable feature that is viability or capability to survive and/or recover. The prior art demonstrate the use of viable microbes capable to survive and recover in probiotic products.

Applicants appear to hypothesize that improvement in the harvested bacteria are due to some biochemical change in the microbes themselves (appeal brief page 5, par. 2). But applicants did not establish any structural differences between final microbes and starting microbes with regard to those "biochemical" changes as argued. The final bacteria are the same as starting bacteria. Moreover, Applicants appear to admit that no structural limitation can be

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added to the microbe themselves (appeal brief page 5, par. 2) and it is also believed that if there would be some changes, applicants would propose a novel microbial strain. Furthermore, Applicants did not establish that biochemical changes, if any, would be permanent. Applicants did not establish that induction of biochemical changes and/or microbial enzymatic activity is not reversible. Applicants did not establish for how long the induction biochemical changes might last. In the instant claims, the product-by-process does not indicate how long bacteria are grown on resistant starches. The claimed invention does not indicate how much of resistant starch would be needed to produce the biochemical changes, if any, as argued. The claimed product is a generic product that is directed to any and all microbes. Thus, the functional effects resulting from culturing generic microbes on resistant starch as claimed cannot be properly analyzed and fully delineated. Therefore, the prior art preparations comprising viable microbes capable to survive and recover in probiotic products including resistant starches cannot be said as being functionally better or worse than the claimed product, or as being functionally different from the claimed generic product.

Applicants argue that they provided evidence in the form of the various examples that microbes harvested from a resistant starch containing culture having improved survival and recovery compared to the same organisms harvested from media without resistant starch as shown in Examples 1-11 and Figs. 1-14 (appeal brief page 7, par. 3). However, the showing is rather uncertain. For example: figures 4-9 demonstrate that after 5-6 days there would be no viable cells and, thus, no survival and recovery of microbial preparations for all tested substrates and/or products. For example: fig. 3 demonstrate that cell count for some strain "C" remains the

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same for all substrates at least within 10 hours. For example: figure 1 demonstrates that viable counts for some strains “E” and “D” are about the same at about 60 hours.

Thus, the showing and arguments based thereon are at the very least ambiguous and confusing as to significance in bacterial productivity and recovery rates as indicated.

A. With regard to the claim rejection under 35 U.S.C. 102(b) as being anticipated by US 5,143,845 (Masuda) some applicants’ argument are relied upon on the contents of Declaration by Ian Brown submitted on February 25, 2005 (attached as Appendix B). The contents of Declaration are drawn to the idea that the potato starch-containing medium used in the product of the cited patent US 5,143,845 (Masuda) was sterilized by autoclave and, thus, there was no resistant starch in the microbial culture media for growing and making microbial preparations as argued (appeal brief page 6).

However, the rejection over US 5,143,845 (Masuda) is only applied to the claims drawn to microbial preparations but not to the claims drawn to composition comprising microbial preparation plus resistant starch.

Moreover, it is at least ambiguous whether or not autoclaving in fact would make resistant starch digestible as stated in Declaration by Ian Brown submitted on February 25, 2005 (items 5, 6) because applicants’ specification, for example: at page 5, lines 1-3, recites that “repeated autoclaving and rapid cooling can also be used to increase the resistant starch content of starches”.

Regardless the fact that different forms of resistant starches might be encompassed as substrates for growing and/or adapting microbes by the process steps in the product-obtained-

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by-process, the end microbial products are no more than viable microbial compositions capable to survive and to recover. Thus, although US 5,143,845 (Masuda et al.) might not use resistant starch and/or various categories of resistant starch for making and harvesting microbes, this fact cannot distinguish between structural and/or material differences of the claimed final product over the final product of US 5,143,845 (Masuda et al.) for generic microbes as claimed. The presently claimed product is defined as a product-by-process. The product-by-process claims are not limited to the manipulations of the recited steps, only to the final structure of the product obtained and the patentability of a product does not depend on its method of production. MPEP 2113. In the instant claims, the final product or final microbial preparation is said to be relatively better over some generic starting microbial cells with respect to microbial survival and recovery. However, neither starting nor end products are particular microbial strains that are available, reliable and characterized by some particular rates of survival or recovery. Thus, in view of a relative characterization that is defined by the structure of the instant claims, the claimed microbial product *per se* has only one final physical or measurable feature such as viability or capability to survive and/or recover. Therefore, the cited “microbial preparation having increased survival /recovery rate” disclosed by US 5,143,845 (Masuda) that is characterized as having enhanced heat, dry and drug stability, that is stress resistant, that is capable to grow on starch or on cooked potato starch and that is taught as suitable for pharmaceutical and food products is within the scope of the claimed product.

With regard to the claim rejection under 35 U.S.C. 102(b) as being anticipated by US 5,143,845 (Masuda) Applicants also argue that the Masuda’s preparations are symbiotic bacterial mixtures, that the Masuda’s preparations contain bacterial spores and that the Applicants’

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composition is neither symbiotic mixture nor microbial spores (appeal brief page 7, last 2 paragraphs). However, instant claims do not exclude spores and it is known that bacteria in form of spores have better survival rates than vegetative forms of bacteria. Further, at least some of the instant claims, for example: claims 96-99, are directed to the use of “combination” of bacteria and, thus, the cited product is not different from the mixture including same bacteria as in the claimed product.

B. With regard to the claim rejection under 35 U.S.C. 102(b) as being anticipated by US 6,060,050 (Brown et al.) in the light of evidence by US 5,714,600 (McNaught et al.).

Applicants argue that the microbes in the product the cited patent are not harvested after culturing on a resistant starch (appeal brief page 8). This is not found persuasive because the cited patent teaches microbial preparations grown on resistant starch, for example: see col. 5, lines 32-36 or figures 9 and 10. Applicants argue that figures 9 and 10 depict the in vitro growth profiles that are lacking “harvested” microbial preparations. This is not found persuasive because figures depict cells number (cells/ml) in liquid medium containing resistant starches and, thus, cells had to be separated from the starch-containing media and, thereby, “harvested” from the starch-containing media for enumeration. Enumeration requires incorporation into another product wherein viable microbes develop colonies as it is also admitted by applicants (appeal brief page 8, last 2 lines). Further, even though the cited patent does not clearly disclose active step of comparing starting and end microbial products, the claimed invention is drawn to the use of generic microbes.

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In response to applicant's argument that the microbes of US 6,060,050 might have been were grown on resistant starch for a different purpose, it is noted that a recitation of the intended use or effects of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The instant claims are drawn to a product comprising two components that are 1) microbes with "increased" capability to survive on resistant starch and 2) resistant starch. The structure of the prior art is a composition comprising 1) microbes capable to utilize resistant starch and 2) resistant starch. Thus, the prior art structure is identical to the structure of the claimed product. Therefore, the prior art structure meets the claim

C. With regard to the claim rejection under 35 U.S.C. 103(a) as being unpatentable over US 5,143,845 (Masuda) taken with US 6,060,050 (Brown et al.), Brown et al. ("High amylase maize starch as a versalite prebiotic for use with probiotic bacteria". Food Australia 50 (12), December 1998) and US 5,714,600 (McNaught et al.) Applicants appear to argue that the prior art is lacking suggestion that culturing on resistant starch would provide microbes with advantages related to improved growth or survival rates (appeal brief pages 9-10).

This is not found persuasive because the cited patent US 6,060,050 (Brown et al.) clearly teaches and suggests to select and harvest bacteria grown on resistant starch (col. 2, lines 14-19) and because the cited reference by Brown et al. clearly teaches beneficial properties of resistant

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starch including improved robustness of probiotic cultures, improved viability of probiotics, enhanced survival/proliferation rates, etc. (table 2) for making microbial probiotic preparations. Thus, the cited prior art as a whole adequately demonstrates suggestion and motivation to combine resistant starch and viable microbial preparations grown on resistant starch and the prior art also demonstrate availability of different forms of resistant starches.

D. With regard to claim rejection under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,221,350 (Brown et al.) Applicants' arguments (appeal brief page 11) are not found persuasive because they are directed to the differences in the intended use of resistant starch in the compositions comprising microbes and resistant starch. Applicants argue that resistant starch in the claims of US 6,221,350 is a carrier and is not used as a substrate to select or to harvest microbes having "increased" recovery/survival rates. However, microbes in the claims of US 6,221,350 (claim 5, for example) belong to the same species as the microbes in the instant claims (claim 96, for example). Moreover, US 6,221,350 discloses that the probiotic microbes of the claimed invention are selected such that they are able to utilize starch as nutritional source (col. 2, lines 36-40). Thus, the claimed inventions are obvious variants.

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For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,



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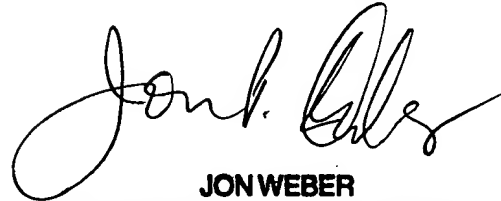


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